Study: CDISCPILOT01 Subject: 01-701-1115 (1115) Status: ADVERSE EVENT

 Demographics

 Country
 Age (y)
 Sex
 Race
 Ethnicity
 Planned Arm
 Actual Arm

 USA
 84
 M
 WHITE
 NOT HISPANIC OR LATINO
 Xanomeline Low Dose
 Xanomeline Low Dose

Page 1 of 2 First Dose Date: 2012-11-30

Current Visit: RETRIEVAL

Subject Visits								
Visit	Visit Day	Visit Date						
SCREENING 1	-7	2012-11-23						
SCREENING 2	-1	2012-11-28						
BASELINE	1	2012-11-30						
AMBUL ECG PLACEMENT	13	2012-12-12						
WEEK 2	14	2012-12-13						
WEEK 4	28	2012-12-26						
UNSCHEDULED 5.1		2012-12-28						
AMBUL ECG REMOVAL	30	2012-12-28						
WEEK 6	42	2013-01-10						
WEEK 8	56	2013-01-23						
AE FOLLOW-UP		2013-02-14						
RETRIEVAL	168	2013-05-20						

Adverse Events										
Sponsor Defined Identifier and Verbatim Term	Start Date (Day)	End Date (Day)	Ser-ious?	Duration (days)	Sever- ity	Relation- ship	Outcome	Action Taken	Treatment Emergent?	
E09: APPLICATION SITE ERYTHEMA	2012-12-02		No		Mild	Probable	Not Recovered/Not Resolved		Yes	
E09: APPLICATION SITE ERYTHEMA	2012-12-02		No		Moderate	Probable	Not Recovered/Not Resolved		Yes	
E10: APPLICATION SITE IRRITATION	2012-12-26 (27)	2012-12-26 (27)	No	1	Mild	Possible	Not Recovered/Not Resolved		Yes	
E10: APPLICATION SITE IRRITATION	2012-12-26 (27)	2012-12-26 (27)	No	1	Mild	Possible	Recovered/Resolved		Yes	
E11: APPLICATION SITE PRURITUS	2012-12-02		No		Mild	Probable	Not Recovered/Not Resolved		Yes	
E11: APPLICATION SITE PRURITUS	2012-12-02		No		Moderate	Probable	Not Recovered/Not Resolved		Yes	
E12: APPLICATION SITE IRRITATION	2013-01-19 (51)		No		Moderate	Probable	Not Recovered/Not Resolved		Yes	
E13: FATIGUE	2013-01-14 (46)		No		Moderate	Remote	Not Recovered/Not Resolved		Yes	
E14: APPLICATION SITE DERMATITIS	2013-01-19 (51)		No		Moderate	Probable	Not Recovered/Not Resolved		Yes	

Study: CDISCPILOT01 Page 2 of 2
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Vital Signs										
Vital Sign Parameter	SCR1	SCR2	BSLN	ECPL	WK02	WK04	ECRM	WK06	WK08	RETR
Diastolic BP (mmHg)	69	68	69	72	69	56	50	69	60	68
Pulse Rate (BEATS/MIN)	61	59	60	65	65	64	60	62	54	94
Systolic BP (mmHg)	131	115	110	116	100	95	99	104	98	99
Temperature (C)	36.3	36.2	36.7	36.3	36.7	36.5	36.3	36.4	36.4	36.3
Weight (kg)	78.7		78.9		78.9	78.5		78.5	78.5	

